K120609

SEP 7 2012

Special 510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

Submitter Information	
Name	Ortho Clinical Diagnostics
Address	100 Indigo Creek Drive, Rochester, NY 14626, USA
Phone number	(585) 453-4041
Fax number	(585) 453-3368
Establishment Registration Number	1319809
Name of contact person	Marlene A. Hanna
Date prepared	February 24, 2012
Name of device	
Trade or proprietary name	VITROS Chemistry Products dHDL Slide
Common or usual name	HDL Cholesterol assay
Classification name	Lipoprotein test system
Classification panel	Clinical Chemistry
Regulation	21 CFR 862.1475
Product Code(s)	LBS
Legally marketed device(s) to which equivalence is claimed	The VITROS Chemistry Products dHDL Slide (modified) are substantially equivalent to the VITROS Chemistry Products dHDL Slides (current slide). The FDA cleared the VITROS Chemistry Products dHDL Slides on October 26, 2004 (k042006).
Reason for 510(k) submission	A Special 510(k) for a modification to own device which does not include a change in intended use or fundamental technology. Each modified VITROS dHDL Slide will have 30% less ingredients compared to the current VITROS dHDL Slide as a result of a smaller surface area. Since the reduction in ingredients per slide is due to a smaller surface area, the concentration of ingredients of the modified slide will be unchanged compared to the current slide. The device modification results in a reduction in the sample volume required per test from 10 µL per test to 6 µL per test.
Device description	The VITROS dHDL assay is performed using the VITROS Chemistry Products dHDL Slide and the VITROS Chemistry Products Calibrator Kit 25 on the VITROS Chemistry Systems. The VITROS dHDL Slide is a multi-layered analytical element coated on a polyester support. The method is based on a non-HDL precipitation method followed by an enzymatic detection. All reactions necessary for a single quantitative measurement of HDLC take place within the multi-layered analytical element of a VITROS Chemistry Products dHDL Slide. A drop of sample fluid is metered onto the slide and a reaction occurs which ultimately generates a colored dye. The density of dye formed is proportional to the HDL Cholesterol concentration present in the sample and is measured by reflectance spectrophotometry.

Intended use of the device	For *in vitro* diagnostic use only. VITROS Chemistry Products dHDL Slides are used to quantitatively measure HDL cholesterol (HDLC) concentration in serum and plasma using VITROS 250/350/950/5,1 FS and 4600 Chemistry Systems and the VITROS 5600 Integrated System. High Density Lipoprotein (HDL) cholesterol is used to evaluate the risk of developing coronary heart disease (CHD). The risk of CHD increases with lower HDL cholesterol concentrations.
Indications for use	High Density Lipoprotein (HDL) cholesterol is used to evaluate the risk of developing coronary heart disease (CHD). The risk of CHD increases with lower HDL cholesterol concentrations.

Summary of the technological characteristics of the device compared to the predicate device

Characteristic	New Device[Modified VITROS dHDL Slide]	Predicate [VITROS dHDL Slide] [k042006]
Intended Use	Same	For *in vitro* diagnostic use only. VITROS Chemistry Products dHDL Slides are used to quantitatively measure HDL cholesterol (HDLC) concentration in serum and plasma using VITROS 250/350/950 and 5,1 FS and 4600 Chemistry Systems and the VITROS 5600 Integrated System. High Density Lipoprotein (HDL) cholesterol is used to evaluate the risk of developing coronary heart disease (CHD). The risk of CHD increases with lower HDL cholesterol concentrations.
Fundamental technology	Same	Dry, multilayered slide utilizing method based on a non-HDL precipitation method followed by enzymatic detection, measured by reflectance spectrophotometry.
Sample Volume Required	6 µL	10 µL
Instrumentation	Same	VITROS 250/350/950 and 5,1 FS and 4600 Chemistry Systems and the VITROS 5600 Integrated System.
Concentration of dHDL Slide Reactive Ingredients per Slide (test)	Same	Emulgen B-66 0.7 mg; phosphotungstic acid 0.3 mg; magnesium chloride 0.2 mg, cholesterol oxidase (Cellulomonas, E.C.1.1.3.6) 0.8 U; cholesterol ester hydrolase (Candida rugosa, E.C.3.1.1.3) 1.2 U; peroxidase (horseradish root, E.C.1.11.1.7) 2.2 U; and 2- (3,5-dimethoxy-4-hydroxyphenyl)-4,5-bis-(4-dimethylaminophenyl) imidazole (leuco dye) 0.02 mg

Amount of dHDL Slide Reactive Ingredients per Slide (test)	Emulgen B-66 0.63 mg; phosphotungstic acid 0.27 mg; magnesium chloride 0.15 mg, cholesterol oxidase (Cellulomonas, E.C.1.1.3.6) 0.72 U; cholesterol ester hydrolase (Candida rugosa, E.C.3.1.1.3) 1.10 U; peroxidase (horseradish root, E.C.1.11.1.7) 2.0 U; and 2- (3,5-dimethoxy-4-hydroxyphenyl)-4,5-bis-(4-dimethylaminophenyl) imidazole (leuco dye) 0.018 mg.	Emulgen B-66 0.90 mg; phosphotungstic acid 0.38 mg; magnesium chloride 0.22 mg, cholesterol oxidase (Cellulomonas, E.C.1.1.3.6) 1.0 U; cholesterol ester hydrolase (Candida rugosa, E.C.3.1.1.3) 1.56 U; peroxidase (horseradish root, E.C.1.11.1.7) 2.82 U; and 2-(3,5-dimethoxy-4-hydroxyphenyl)-4,5-bis-(4-dimethylaminophenyl) imidazole (leuco dye) 0.026 mg
Sample Type	Same	Serum, plasma
Measuring Range	Same	5.0 – 110.0 mg/dL
CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA		
The information presented in the premarket notification provides a reasonable assurance that the VITROS Chemistry Products dHDL Slides (modified) for use with human serum and plasma is substantially equivalent to the predicate (unmodified VITROS dHDL Slide) and is safe and effective for the stated intended use.		

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 26, 2012

Ortho-Clinical Diagnostics, Inc.
c/o Marlene Hanna
100 Indigo Creek Drive
Rochester, NY 14626-5101

Re: k120609
Trade Name: VITROS Chemistry Products dHDL Slides
Regulation Number: 21 CFR §862.1475
Regulation Name: Lipoprotein Test System
Regulatory Class: Class I, meets limitations of exemption 862.9 (c)(4)
Product Codes: LBS
Dated: August 9, 2012
Received: August 10, 2012

Dear Ms. Hanna:

This letter corrects our substantially equivalent letter of September 7, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson
for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics and
Radiological Health
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K120609

Device Name: VITROS Chemistry Products dHDL Slides

Indication For Use: For *in vitro* diagnostic use only. VITROS Chemistry Products dHDL Slides are used to quantitatively measure HDL cholesterol (HDLC) concentration in serum and plasma using VITROS 250/350/950/5,1 FS and 4600 Chemistry Systems and the VITROS 5600 Integrated System. High Density Lipoprotein (HDL) cholesterol is used to evaluate the risk of developing coronary heart disease (CHD). The risk of CHD increases with lower HDL cholesterol concentrations.

Prescription Use __X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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